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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,874	04/02/2004	Douglas Schein	115616	9059

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EXAMINER	
BOWERS, NATHAN ANDREW	
ART UNIT	PAPER NUMBER
1797	
MAIL DATE	DELIVERY MODE
12/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/815,874	SCHEIN ET AL.	
	Examiner	Art Unit	
	NATHAN A. BOWERS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *27-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1-3, 7-22, 26 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toledo-Pereyra (US 4186565) in view of Cannon (US 20080032398).

With respect to claims 1-3, 7, 13-15, 22 and 47, Toledo-Pereyra discloses an apparatus for holding an organ (Figure 2:K) comprising a portable housing (Figure 2:14) defining one or more openings and a tube frame (Figure 2:15) removably connectible to the portable housing. Column 1, line 51 to column 2, line 60 indicates that fluids located within the tube frame are transported to the portable housing using a system of tubes. The plurality of tubes in the tube frame are in communication with a plurality of tubes located within the portable housing in order to effectively introduce and withdrawn fluid to and from the organ. Toledo-Pereyra, however, does not expressly indicate that the tubes are attached to the tube frame at respective predetermined positions.

Cannon discloses a portable housing for culturing tissue cells. The portable housing includes a frame assembly (Figure 3) upon which a bioreactor is connected to fluid sources and other unit operations using a plurality of tubes (see Figure 6). Paragraph [0062] states that the tubing is secured to the frame assembly using clips or any other fastener means capable of sufficiently securing the fluid path.

Toledo-Pereyra and Cannon are analogous art because they are from the same field of endeavor regarding tissue treatment systems.

At the time of the invention, it would have been obvious to provide the tube frame assembly of Toledo-Pereyra with clips and fasteners capable of holding each of the plurality of tubes at a desired position. This would have been a beneficial way to ensure that the flow paths do not become tangled or crushed during operation. Cannon is evidence that clips of this kind are well known in the art as effective means to organize fluid media tubes at predetermined positions within a frame assembly.

With respect to claim 8, Toledo-Pereyra and Cannon disclose the apparatus in claim 1 wherein a pressure sensor capable of determining fluid pressure is connectable to the tube frame. This is described by Toledo-Pereyra in column 2, lines 37-40.

With respect to claims 9 and 10, Toledo-Pereyra and Cannon disclose the apparatus in claim 1. Furthermore, Toledo-Pereyra discloses that a bubble trap (Figure 2:17) is connectable to the tube frame and in communication with tubes located in the portable housing and the tube frame.

With respect to claims 11 and 12, Toledo-Pereyra and Cannon disclose the apparatus in claim 1 wherein the plurality of tubes in the portable housing are connectible to an organ (Figure 2:K). Column 1, line 61 of Toledo-Pereyra states that tubes delivering fluid to the organ are connected to the organ. This is depicted in Figure 2.

With respect to claims 16 and 17, Toledo-Pereyra and Cannon disclose the apparatus in claim 1 wherein the portable housing and the tube frame are each supported by an organ transportation device (Figure 1:11 and Figure 1:10).

With respect to claims 18-21, Toledo-Pereyra and Cannon disclose the apparatus in claim 17 wherein a pump (Figure 3:20) is provided for transporting fluids through the plurality of tubes found in the portable housing and the tube frame. This is disclosed by Toledo-Pereyra in column 1, lines 63-65. Toledo-Pereyra describes the use of peristaltic roller type pumps.

With respect to claim 26, Toledo-Pereyra and Cannon disclose the apparatus in claim 1 wherein the tube frame is made of plastic. This is described by Toledo-Pereyra in column 1, lines 54-57.

2) Claims 4-6 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toledo-Pereyra (US 4186565) in view of Cannon (US 20080032398) as applied to claims 1 and 17, and further in view of Fahy (US 5586438).

With respect to claims 4 and 5, Toledo-Pereyra and Cannon disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejection above, however do not expressly state that an organ supporting surface is located within the portable housing.

Fahy discloses a portable device for preserving organs that comprising a holding chamber (Figure 1:11) in communication with perfusion means (Figure 1:119,120,110). Fahy teaches in column 4, lines 7-19 that soft pads (Figure 1:13,14) are provided supporting an organ or tissue.

Toledo-Pereyra and Fahy are analogous art because they are from the same field of endeavor regarding organ holding apparatuses.

At the time of the invention, it would have been obvious to utilize an organ supporting surface in the apparatus of Toledo-Pereyra. Fahy teaches that soft foam surfaces conform to the contour of the organ transported thereon, and thereby prevent bruising and physical damage. Soft foam surfaces are inexpensive and prevent lateral motion of the organ within the portable housing.

With respect to claim 6, Toledo-Pereyra and Cannon disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejection above, however do not expressly state that a filter is in communication with the plurality of tubes in the portable housing.

Fahy discloses the apparatus as previously described above. Fahy further indicates that a filter (Figure 1:121) is in communication with tubing adapted to supply and withdraw fluid to and from the organ. This is described in column 7, lines 15-22.

At the time of the invention, it would have been obvious to include a filter device in the perfusion system disclosed by Toledo-Pereyra. Fahy teaches that filter assemblies are beneficial because they remove undesirable particulates from fluids moving to the preserved organ. Fahy states that it is "very desirable to continuously filter perfusate to guard against any inadvertent introduction of microorganisms in any manner into the container."

With respect to claims 23-25, Toledo-Pereyra and Cannon disclose the apparatus set forth in claim 17 as set forth in the 35 U.S.C. 102 rejection above, however do not expressly state that a sensor is provided for detecting proper and improper connection between the tube frame and the organ transporter.

Fahy discloses a lid position sensor capable of detecting when the lid of the organ holding chamber is ajar. Column 13, lines 16-35 state that when the lid is determined to be in an undesirable position, the sensors will convey this information to an operator through the use of an alarm or visual display.

At the time of the invention, it would have been obvious to include a detection system capable of determining when the tube frame of Toledo-Pereyra is improperly connected to the

organ transporter. This would have been beneficial because it would have prevent possible damage to the organ resulting from mechanical failures resulting from improper connections. By ensuring that each component is properly connected to the other components, one would have been able to prevent tampering with the organ or excessive heat or contaminant infiltration.

Response to Arguments

Applicant's arguments filed 16 September 2008 with respect to the 35 U.S.C. 102 rejections involving Toledo-Pereyra have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration, a new ground of rejection is made in view of the combination of Toledo-Pereyra in view of Cannon.

Cannon addresses the deficiencies of Toledo-Pereyra by indicating that it is known in the art to attach tubes to a frame assembly in predetermined positions using fastening devices. The use of these clips would have been a beneficial way to ensure that the flow paths of Toledo-Pereyra do not become tangled or crushed during operation.

Applicant's further asserts that Toledo-Pereyra does not disclose a tube frame that is configured to hold the plurality of tubes in a position to be connected to a plurality of tubes in the portable housing because the tubes of Toledo-Pereyra's second portion travel to an external refrigerator before moving to the organ chamber.

In response, the claims do not require a direct connection between the portable housing and the tube frame. Rather, the claims merely state that the "tube frame is configured to hold the plurality of tubes in a position to be connected to a plurality of tubes in the portable housing." In

Toledo-Pereyra, fluid from the tube frame is moved to the portable housing using tubes located in the portable housing and the frame assembly. Accordingly, the tubes are connected. The tubes remain in fluid communication even though the medium is moved through an external refrigerator when being transported from the tube frame to the portable housing. Likewise, the tubes remain in fluid communication even though the medium is moved through an oxygenator when being transported from the portable housing back to the tube frame.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/Nathan A Bowers/
Examiner, Art Unit 1797